

In re: Caligiuri *et al.*

Appl. No.: 09/855,342

Filed: May 14, 2001

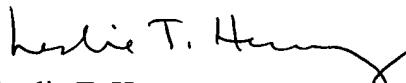
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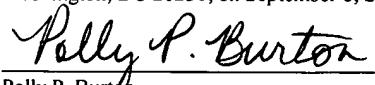
REMARKS

The specification has been amended at page 28 as noted above to remove an obvious typographical error. The sentence as amended on page 28 correctly reflects the sentence as set forth in the priority document, U.S. Provisional Application Serial No. 60/204,284, at page 28, line 17, of the specification. No new matter is added by way of amendment.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

  
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**Version With Markings to Show Changes Made:**

**In the Specification:**

Please rewrite the paragraph at page 28, line 23 to read as follows:

In a phase II study (see reference 11 of the CALGB 9661 Protocol), humanized anti-HER2 was administered to 46 patients with metastatic breast cancer at a weekly intravenous dose of 100 mg following a loading dose of 250 mg. Objective responses were seen in 5 of 43 assessable patients (11.6%), with stable disease reported in 16 additional patients. Antibody trough levels of at least 10  $\mu$ g/ml were obtained in more than 90% of patients. The mean serum antibody half-life was  $8.3 \pm [??]$  5.0 days. Human anti-human antibodies were not detected in this study. Toxicity was unusual in this study. Eleven moderate-severe toxic events occurred in 768 antibody administrations. These toxicities included fever and chills (5 patients), pain at tumor site (3 patients), diarrhea (2 patients), and nausea and vomiting (1 patient).